

## REMARKS

All pending claims have been canceled without prejudice or disclaimer. Claims 24-49 have been added and therefore are pending in the present application. Claims 24-49 are supported throughout the specification, including the original claims.

Applicants also enclose a substitute Sequence Listing. The substitute Sequence Listing is identical to the previously-submitted Sequence Listing, except that the three amino acids "RWL" have been added at the end of SEQ ID NO: 1. This submission contains no new matter.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I. The Objection to Claim 26

The Office objected to claim 26 under 37 CFR 1.75 because there were no claims 23-25. The Office is correct that claim 26 should have been numbered 23. All of the original claims have been canceled, and the new claims have been numbered beginning with claim 24. Applicants therefore submit that this objection has been overcome.

### II. The Rejection of Claims 1, 2, 10, 11, and 13-15 under 35 U.S.C. 112

Claims 1, 2, 10, 11, and 13-15 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office objected to (x) claim 1 because it is unclear what the preliminary amendment intended to delete from this claim and (y) claim 2 because of the recitation "consisting of".

All of the pending claims have been canceled without prejudice or disclaimer in order to address this rejection. Applicants therefore submit that this rejection has been overcome.

### III. The Rejection of Claim 2 under 35 U.S.C. 112

Claim 2 is rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. This rejection is respectfully traversed.

It is well settled that "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter ..." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See *In re Marzocchi*, 169 U.S.P.Q. 367 (C.C.P.A. 1971).

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

Applicants respectfully submit that the claims of the instant application comply with the written description requirement under 35 U.S.C. 112, first paragraph.

Claim 2 is directed to polypeptides having antimicrobial activity with a sequence of 18 amino acids optionally extended by the amino acids R-W-L. Persons skilled in the art are able to list the amino acid sequences of all of the polypeptides of claim 2. Moreover, the specification discloses nine polypeptides within the scope of claim 2, namely, SEQ ID NOS: 38 to 46.

Applicants therefore submit that claim 2 satisfies the requirement for written description under 35 U.S.C. 112, first paragraph.

However, in order to advance prosecution, claim 2 has been canceled without prejudice or disclaimer. Therefore, this rejection is rendered moot.

#### **IV. The Rejection of Claims 14 and 15 under 35 U.S.C. 112**

Claims 14 and 15 are rejected under 35 U.S.C. 112 "because the specification, while being enabling for the use of specific polypeptides as an antibiotic against specific microbes, does not reasonably provide enablement for the use of all the polypeptides against any and all microbes." This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of

experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

Applicants submit that the specification complies with the enablement requirement.

Claims 14 and 15 are drawn to polypeptides having antimicrobial activity. The specification at, e.g., page 25, lines 6-21 discloses a number of microbes against which the polypeptides can be used. Furthermore, the specification contains examples demonstrating that 45 different polypeptides of the present invention are effective against *Pseudomonas aeruginosa* and that one of the polypeptides is also effective against *Bacillus subtilis* and *Eschericia coli*. Based on these data, persons skilled in the art would expect that the polypeptides of the present invention are effective against other microbes. Moreover, it would be routine for persons of ordinary skill in the art to test the polypeptides of the present invention for their antimicrobial activity against other microbes.

Moreover, the Office has not provided any evidence that the polypeptides are not active against microbes. For example, the Office relies on Vant Hof as teaching that specific peptides that are active on bacteria are not necessarily active on fungi and on Nagarajan as teaching that the effect of changes on antibiotics is difficult to predict. However, neither of these references provides any data for the polypeptides of the present invention. Applicants therefore submit that they are not relevant.

However, in order to advance prosecution, claims 14 and 15 have been canceled without prejudice or disclaimer. Therefore, this rejection is rendered moot.

#### **V. The Rejection of Claims 1, 2, 10, 14 and 15 under 35 U.S.C. 101**

Claims 1, 2, 10, 14 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 2, 10, 14 and 15 have been canceled without prejudice or disclaimer. Furthermore, the newly presented claims are directed to "isolated" polypeptides. Applicants therefore submit that this rejection has been overcome.

**VI. The Rejection of Claims 1, 10 and 13-15 under 35 U.S.C. 102**

Claims 1, 10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hong et al. (Biochemical and Biophysical Research Communications, 276: 1278-1285 (2000)). This rejection is respectfully traversed.

Hong et al. disclose an antimicrobial peptide with the amino acid sequence: GILSKLGKALKKAAKHAAGA.

However, Hong et al. do not disclose an antimicrobial peptide comprising an amino acid sequence of SEQ ID NO: 1 recited in claim 24, which has Arg, Cys, Gly, Leu, Phe, Pro, Tyr or Val at position 18.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VII. The Rejection of Claim 2 under 35 U.S.C. 102**

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipate by Huttner et al. (Gene 206: 85-91 (1998)). This rejection is respectfully traversed.

Huttner et al. disclose an antimicrobial peptide having an amino acid sequence with more than 160 amino acids, which ends with the sequence LPWRPPRPPIRPQPQPIPRWL.

However, Huttner et al. do not disclose an antimicrobial peptide comprising an amino acid sequence recited in claim 24 or 36.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VIII. The Rejection of Claims 1, 10, 11, and 13-15 under 35 U.S.C. 103**

Claims 1, 10, 11, and 13-15 are rejected under 35 U.S.C. 103 as being unpatentable over Hong et al. (Biochemical and Biophysical Research Communications 276: 1278-1285 (2000)) and Bycroft et al. (U.S. Patent No. 5,043,176). This rejection is respectfully traversed.

As discussed above, Hong et al. do not teach or suggest the antimicrobial peptides of the present invention.

Bycroft et al. disclose an antimicrobial composition comprising an antimicrobial peptide and a hypothiocyanate component. Bycroft et al. further disclose that examples of the antimicrobial peptide are magainin I, magainin II, cecropins, sarcotoxins, and lantibiotics such as nisin, subtilin, colicin E1, PEP-5, and pediocin.

However, like Hong et al., Bycroft et al. do not teach or suggest the antimicrobial peptides of the present invention.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IX. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: October 2, 2008

/Elias Lambiris, Reg. # 33728/  
Elias J. Lambiris, Reg. No. 33,728  
Novozymes North America, Inc.  
500 Fifth Avenue, Suite 1600  
New York, NY 10110  
(212) 840-0097